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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,830	09/24/2001	Anthony Patrick Jones	PG3614USW	4156

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
MITCHELL, TEENA KAY	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,830	JONES ET.AL.	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/05/04 has been entered.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

It is suggested that HEADINGS be placed appropriately throughout the specification as outlined above.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one or more sensors fro sensing the pressure profile associated with the breath cycle; one or more sensors for sensing the airflow profile; one or more sensors for sensing moisture profile; one or more sensors for sensing oxygen or carbon dioxide profile; electronic information processor; active memory; predictive algorithm, look up table; a dose memory; a selector with a timing mechanism; metering chamber having a telescopic or concertina arrangement; an energy store; spring; voltaic cell; physically explosive energy store; safety mechanism; release counter; a multi-fire mechanism must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. **Determining the scope and contents of the prior art.**
2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et.al. (5,404,871) in view of Hillsman (4,984,158).

Goodman in a portable, hand-held, patient-operable device (Col. 6, lines 28-38) for the delivery of inhalable medicament discloses: a housing adapted to be carried by a patient breathing without the assistance of a respirator and sized to fit within the patient's hand while said device is in use by the patient; a monitor (3400) for monitoring the breath cycle of a patient positioned within said housing; a medicament container (3200) having a release mechanism releasing inhalable medicament therefrom; and an actuator (3150) for actuating said release mechanism, said actuator being actuable in response to a signal from said monitor.

The difference between Goodman and claim 1 is the monitor providing a signal at a trigger point, which is correlated, to the end of the exhalation part of the breathing cycle.

Hillsman in a MDI teaches such a manner of a signal at a trigger point, which is correlated, to the end of the exhalation part of the breath cycle is known to those skilled in the art of respiratory physiology (Col. 8, lines 1-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the monitor provide a signal at a trigger point which is correlated to the end of the exhalation part of the breath cycle as such is well known in the art as taught by Hillsman.

With respect to claim 2, Goodman discloses sensors for sensing the pressure profile associated with the breath cycle (Col. 20, lines 44-68 and Col. 21, lines 1-19).

With respect to claim 3, Goodman discloses sensors for sensing the airflow profile associated with the breath cycle (Col. 20, lines 44-68 and Col. 21, lines 1-19).

With respect to claim 4, Goodman discloses sensor for sensing the temperature profile associated with the breath cycle (Col. 21, lines 20-22).

With respect to claim 5, Goodman discloses substantially the claimed invention except for the use of a moisture sensors to monitor the profile, a known interchangeable equivalent with the pressure sensors in the respiratory arts for performing this function. It is noted that applicant's specification does not set forth this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere design consideration and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art and one of ordinary skill in the art would consider such to amount to a matter of design consideration.

With respect to claim 6, note rejection of claim 5 above.

With respect to claim 7, Hillsman teaches the trigger point corresponds to the point at which the lungs of the patient are most empty (note rejection of claim 1 above).

With respect to claim 8, Goodman discloses wherein the monitor is connectable to an electronic information processor (2000).

With respect to claim 9, Goodman discloses an active memory for storing information the breath cycle (2100).

With respect to claim 10, Goodman discloses a predictive algorithm to predict an optimal triggering point (note claim 1).

With respect to claim 11, Goodman discloses a look-up table for predicting the optimum trigger point (note claim 1).

With respect to claims 12 and 13,Goodman discloses the claimed invention except for the use of a second algorithm or look-up table (i.e, the duplication of a known part for a known purpose).

It is noted that the applicant's specification does not set forth this duplication of a known part as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art of Goodman. Accordingly, the examiner considers the selection of a duplication of a known part for a known purpose to be a mere obvious matter of design consideration and as such does not distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

With respect to claim 14, Goodman discloses a dose memory (2100 and supporting text).

With respect to claim 15, Goodman discloses a display (Col. 6, lines 3-27).

With respect to claim 16, Goodman discloses a selector for selecting the amount of medication to release (Col. 6, lines 28-38).

With respect to claim 17, Goodman discloses wherein the selector is manually operable (because the device can be remotely changed it would be inherent that the selector is manually operable).

With respect to claim 18, Goodman discloses the selector is operable in response to a signal from the electronic information processor (2000).

With respect to claim 19, Goodman discloses a timing mechanism (3400).

With respect to claim 20, Goodman discloses a metering mechanism between the container (3200) and the release mechanism (3210) for metering a variable quantity of medicament for release (3400).

With respect to claim 21, Goodman discloses a multiple-fire mechanism (2000) for multiple actuation of the actuator, wherein each actuation releases a portion of the optimum amount of medicament.

With respect to claim 22, Goodman discloses a medicament container (3200) is an aerosol container containing a medicament formulated in a pressurized liquid propellant and said release mechanism (3210) is an aerosol valve.

With respect to claim 23, Goodman discloses a metering chamber (3124) for metering the release of medicament.

With respect to claim 24, Goodman discloses the metering chamber has a variable metering volume (based on the container and the medicament delivered the chamber would inherently have a variable metering volume).

With respect to claims 25-27, note rejection of claim 5 above.

With respect to claim 28, Goodman discloses wherein the medicament container (3200) is a liquid container.

With respect to claim 29, Goodman discloses wherein the actuator comprises an energy store for storing energy which energy is releasable to activate the release mechanism of the medicament (3150).

With respect to 30, Goodman substantially discloses the claimed invention except for a biasable resilient member. It is noted that applicant has not set forth the use of the resilient member provides any unexpected new result or solves any known problem in the prior art. Accordingly, the examiner considers the use of a resilient member to be a mere obvious matter of design consideration and as such does not distinguish the claims over the prior art of Goodman, barring convincing evidence to the contrary.

With respect to claim 31, note rejection of claim 30 above.

With respect to claim 32, Goodman discloses a source of compressed fluid (3200).

With respect to claim 33, Goodman substantially discloses the claimed invention except for the use of voltaic cell (s) as an energy store, a known interchangeable

equivalent with compressed gas pneumatic energy store in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth the use of known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design consideration and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

With respect to claims 34 and 35, note rejection of claim 33 above.

With respect to claim 36, Goodman discloses a safety mechanism to prevent unintended multiple actuations of the actuator (2000, Col. 34, lines 48-66).

With respect to claim 37, note rejection of claim 5 above.

With respect to claim 38, Goodman discloses an actuation counter (Col. 27, 37-50).

With respect to claim 39, Goodman discloses a medicament release counter (Col. 27, lines 37-50).

With respect to claim 40, Goodman discloses a manual override (2043).

With respect to claim 41, Goodman discloses a housing and a system according to claim 1 (note rejection of claim 1 above).

With respect to claims 42-44 the claimed method steps would have been obvious because they would have resulted from the use of the device disclosed above with respect to Goodman.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show medicament devices 6,260,549; 5,809,997.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached Monday-Friday, however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell
Examiner
Art Unit 3743
November 22, 2004